UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,
Plaintiff,
v. **CIVIL ACTION NO. 3:17-01362**

AMERISOURCEBERGEN DRUG CORPORATION, et al.,
Defendants.

CABELL COUNTY COMMISSION,
Plaintiff, ***Consolidated case:***
v. **CIVIL ACTION NO. 3:17-01665**

AMERISOURCEBERGEN DRUG CORPORATION, et al.,
Defendants.

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT HOLDING THAT CARDINAL HEALTH DID NOT COMPLY WITH ITS DUTIES UNDER THE CONTROLLED SUBSTANCES ACT

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INTRODUCTION

Plaintiffs, Cabell County Commission and City of Huntington, file this memorandum in support of their motion for partial summary judgment holding that Defendant Cardinal Health ("Cardinal") did not comply with its duties under the federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq*. ("CSA").[1]

The CSA and its implementing regulations require Cardinal to maintain effective controls against diversion. More specifically, Defendants are under a duty to report suspicious orders to the Drugs Enforcement Administration ("DEA") and to refrain from shipping such orders that have not been cleared through investigation; instead, they must block those orders until they can determine that diversion is unlikely.[2]

From at least the mid-1990's to 2008, Cardinal reported suspicious orders through submission to the DEA of Ingredient Limit Reports ("ILRs"). ILRs are monthly summaries of controlled substances (including opioids) shipped during the prior month. Cardinal considered the orders reflected in the ILRs suspicious orders. These monthly summaries, however, did not satisfy Cardinal Health's obligations

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[1] Cardinals' duties under the CSA were the subject of several motions filed by the Plaintiffs in the MDL. *See* Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act (Doc. 1887), Motion for Partial Summary Adjudication against Manufacturer and Distributor Defendants (Doc. 1910); and Plaintiffs' Motions in Limine (MDL Doc. 2652). Judge Polster granted Plaintiffs' motions in part and denied them in part. *See* Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, MDL Doc. 2483 (Aug. 19, 2019) ("SOMs Order") (Exhibit 1); Evidentiary Order, MDL Doc. 3052, pp. 24-26 (Dec. 26, 2019) (Exhibit 2). These various rulings will be addressed below.

[2] *See* Section II, *infra*

under the CSA to refrain from shipping suspicious orders that had not been cleared through due diligence. Because the ILRs were not even generated until after the orders had already shipped, the orders could not possibly have been investigated or cleared prior to shipment. Cardinal was aware that the reports did not satisfy its obligations under the CSA but nonetheless relied on, and submitted, after-the-fact ILRs as its suspicious order reports until 2008.

Based on these undisputed facts, this Court should grant partial summary judgment holding that Cardinal's shipment of suspicious orders, none of which were cleared through due diligence, constituted a violation of the CSA and that Cardinal's opioid shipments during this period were in violation of its obligations under federal law.

STATEMENT OF FACTS

I. Regulatory Background

The CSA requires distributors like Cardinal to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty").[3] The CSA defines suspicious orders to

[3] *See* 21 C.F.R. § 1301.74; *In re Nat'l Prescription Opiate Litig.*, 1:17-md-02804-DAP, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213 (D.C. Cir. 2017); *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007).

include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[4]

II. Cardinal shipped suspicious orders of opioid products from 1996 to 2008 without conducting due diligence.

It is undisputed that from at least the mid-1990's until 2008, Cardinal relied on ILRs to identify and report suspicious orders.[5] The ILRs were generated at the end of each month, after the orders had already been shipped. The generation of these after-the-fact reports made it impossible for Cardinal to comply with the no-shipping duty.

Cardinal has produced ILRs that were purportedly submitted to the DEA by its Wheeling, West Virginia distribution center for each month from August 2005 through December 2007 and April 2008.[6] Prior to 2008, Cardinal primarily identified

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[4] 21 C.F.R. § 1301.74(b).

[5] Reardon Dep. of Nov. 30, 2018, 424:9-17; 425:3; 429: 3-10. (Exhibit 3).

[6] *See* CAH ILR Summary (Exhibit 4). Plaintiffs proffer this summary pursuant to Fed. R. Evid 1006. The summary is drawn from the ingredient limit reports produced by Cardinal in this litigation. *See Cardinal's Supplemental Objections and Responses to Plaintiffs' Sixth Combined Discovery Requests, Appendix A: Documents Reflecting Ingredient Limit Reports for City of Huntington and Cabell County Customers* (Exhibit 5). Cardinal has agreed to the admissibility of the underlying documents. The ingredient limit reports themselves are voluminous (totaling thousands of pages as each report ranges from 400 to 600 pages). A Rule 1006 summary may be used as evidence in support of a summary judgment motion. *Tipple Enter., LLC v. Kingsford Mfg. Co.,* No. 1:13CV146, 2014 WL 4925212, at *2 (N.D.W. Va. Sept. 30, 2014) (allowing summary as evidence of voluminous writings could not "be conveniently examined in court" to support summary judgment motion). The requirements of the rule are met here where the underlying documents are voluminous, and which were produced by Cardinal. *See* Fed. R. Evid 1006 (The proponent may use a summary, chart, or calculation to prove the content of voluminous writings. . . that cannot be conveniently examined in court. The proponent must make the originals or duplicates

suspicious orders – and reported them to the DEA -- after they had already been shipped in the form of these monthly summaries. The reports detailed orders for the previous month and were generated and submitted to the DEA after the month ended. The monthly reports showed which orders of controlled substances Cardinal received exceeded a pre-determined average that had been multiplied by four for Schedule II drugs.[7]

If a customer's orders are included in an ILR, it is because for that month, the customer's total orders of that drug exceeded the limit for a drug base code.[8] For each "ingredient limit" a pharmacy exceeds, the report contains a listing of all orders for that drug for the month, not just the ones in excess of the limit. Orders that were considered in excess of the limit were considered suspicious orders.[9]

It is undisputed that Cardinal did not conduct any due diligence on the suspicious orders it identified through its ILR process prior to shipping the orders. As Cardinal's former Vice President of Quality and Regulatory Affairs, Steve Reardon

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available for examination or copying, or both, by other parties at a reasonable time and place.").

[7] Because they were based on volume alone, the ILRs also likely failed to identify orders deviating substantially from a normal pattern and orders of unusual frequency. *See* 21 C.F.R. § 1301.74(b).

[8] The base code for oxycodone hydrochloride, for example, is 9143, codeine is 9050, and hydrocodone is 9193.

[9] Reardon Dep. of Nov. 30, 2018, 426:16-24-428:3 (Ex. 3); *see also Cardinal's Supplemental Objections and Responses to Plaintiffs' Sixth Combined Discovery Requests, Appendix B: Custodial Documents Reflecting Suspicious Order Reports for City of Huntington and Cabell County Customers* (Ex. 6).

testified, the only due diligence that was conducted on these identified suspicious orders was through reviewing the ILRs after the order had been shipped:

> Q. You -- you've explained that process. And if we're shipping suspicious orders, we need to do some sort of due diligence to make sure that it's okay still to ship them?
>
> Q. Right?
>
> A. That's what the review of the report did.
>
> Q. Well, let's talk about that because we're not reviewing the report until the pills have already gone, correct?
>
> A. Correct.
>
> Q. So Mr. Papantonio has shown you earlier the amount, that the tens, if not hundreds of thousands, of pills that were being ordered by some of these pharmacies every month. But by the time we're reviewing the report, those pills are already gone and out on the street, aren't they?
>
> A. Correct.
>
> Q. It's not an effective system to prevent diversion if we've already sent out the pills, and then we're reviewing the report, is it?
>
> A. It could be suspect; we could prevent it.[10]

ILRs were retrospective, detailing orders for the previous month, and were generated and submitted to the DEA after the month ended. Because the identified orders had already been shipped to their respective customers,[11] it would have been

[10] Reardon Dep. of Nov. 30, 2018, 452:1-24-453:1-6 (counsel objections omitted) (Ex. 3); *see also id.* at 449:24-450:1-6 (Reardon agreeing that Cardinal "believed our obligation was just to send in orders [to the DEA]").

[11] *Id.* at 427:17-428:6.

impossible to conduct any due diligence on the orders identified on the ILRs prior to shipping. Cardinal does not contend otherwise.

III. Cardinal understood its obligations under the CSA.

Cardinal's Rule 30(b)(6) designee, Jennifer Norris, testified that Cardinal was made aware of the requirement not to ship suspicious orders was when it received the DEA's September 27, 2006 letter providing guidance regarding its obligations under the CSA.[12] Ms. Norris acknowledged that the 2006 DEA letter provided Cardinal with instructions regarding the shipping requirement, prohibiting the shipment of suspicious orders.[13] Ms. Norris further acknowledged that she was aware that the failure to comply with the guidance provided in the DEA's September 27, 2006 letter would result in unlawful conduct violating the statute, regulations, and DEA's guidance.[14]

Ms. Norris further acknowledged that, as early as September of 2006, Cardinal Health was aware that reporting suspicious orders did not mean that it was meeting the requirement to maintain "effective programs to detect and prevent diversion."[15] Nonetheless, Ms. Norris admitted that Cardinal's anti-diversion suspicious order

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[12] Testimony of Jennifer R. Norris, 136: 11-16, (1:17-MD-2804)(August 7, 2018) (Ex. 7); *see also* Doc. 1910-1, Ex. 11, Norris Depo., 171:20-172:1; 173:23-174:4 (*Id.*).

[13] *Id.* at 171: 20-24; 172: 1-8 ("Do you agree that on September 27, 2006, Cardinal Health got instructions with a new requirement called the shipping requirement? . . . A: Yes. Q: And from that point forward, that was the law in the United States of America according to Cardinal? . . . A: Yes.").

[14] *Id.* at 172: 9-22 (admitting Cardinal's practices may constitute "engaging in activities that do not comply with the statute, regulations, and DEA's guidance").

[15] *Id.* at 295: 20-24; 296: 1-24; 297: 1-4.

monitoring program, that was compliant with DEA guidelines, was not implemented until at least late 2007.[16]

IV. Cardinal ignored its obligations under the CSA and shipped and distributed excessive amounts of opioids into Huntington and Cabell County

Despite its obligations, Cardinal continued to ship suspicious orders and to identify and investigate them (if at all), only after the fact. For instance, on August 5, 2007, Cardinal generated a 535-page ILR covering shipments from its Wheeling distribution facility which documented each pharmacy which ordered more than four times the average base weight of controlled substances for the month of July.[17]

The July 2007 IRL flagged The Medicine Shoppe in Huntington (WV). Cardinal converted the number of pills into a base weight of oxycodone and "reported" to the DEA that it had shipped The Medicine Shoppe 363 grams of oxycodone. Cardinal's ingredient limit for oxycodone was 116 grams (which was four times the amount for the average pharmacy). Cardinal shipped to The Medicine Shoppe more than twelve times the average customer amount in July 2007.[18]

A summary of the ILR Reports produced by Cardinal shows shipments in excess of Cardinal's ingredient limits to six Cabell County/Huntington pharmacies.[19]

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[16] *Id.* at 300:2-8. While she testified about the late 2007 implementation, Cardinal's institutional memory of its exact actions is less than clear. *Id.* at 293:17-24; 294: 1-5.

[17] CAH_MDL_PRIORPROD_DEA07_01120515 (Exhibit 8).

[18] By June 12, 2012, internal Cardinal communications referred to The Medicine Shoppe as a "black hole." CAH_MDL2804_03309972. Nonetheless, Cardinal continued to ship opium pills to this customer. (Exhibit 9).

[19] *See* CAH ILR Summary (Exhibit 4) (noting shipments to the following Pharmacies (*K-Mart,* Huntington, W.Va.; *Continuum Care,* Huntington, W.Va.; *Medical*

In spite of the fact that the orders exceeded Cardinal's ingredient limit for the Wheeling Distribution Center, from August 2005 through December 2007 and April 2008, Cardinal shipped opioids to these six Cabell/Huntington pharmacies that triggered the ILR Reports. The excess shipments from 239 invoiced orders contained 3,631,990 milligrams of opioids comprising 248,044 dosage units. Many of the orders were substantially in excess of the applicable ingredient limits. For example, ten shipments to the Med Associates Pharmacy in Huntington resulted in excess dosage units in the range of 1,000 to 20,000.[20]

ARGUMENT

I. Cardinal's Failure to Properly Identify Suspicious Orders and Its Shipment of Suspicious Orders Without Due Diligence Constitutes a Violation of the Controlled Substances Act.

Under the CSA, Cardinal was under a duty to maintain effective controls against diversion. That duty required Cardinal to identify and report suspicious orders and to halt shipments of such orders pending investigation. As Judge Polster noted before this case was remanded:

> In sum, the Court concludes that the CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty

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Associates, Barboursville, Cabell County, W.Va.; *CVS Twentieth Street*, Huntington, Cabell County, W.Va.; *CVS Fifth Avenue*, Huntington, Cabell County, W.Va.; and *Medicine Shoppe,* Huntington, W.Va.). Cardinal has only produced ILRs for the period of time from August 2005 through December 2007 and April 2008. The total number of suspicious orders shipped to Cabell/Huntington would likely be substantially higher if the ILRs dating back to 1994 when Cardinal began to use the ILR process.

[20] *Id.*

> not to ship suspicious orders. Indeed, given the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion. [21]

There is no factual dispute that Cardinal relied entirely on ILRs to identify and report suspicious orders, and that the ILRs were generated after the orders in question had already been shipped. From these undisputed facts, the Court can readily conclude that Cardinal's failure to identify and investigate suspicious order prior to shipping them constituted a violation of the CSA.

Cardinal, by its own admission, did not have a policy to stop shipment of suspicious orders until sometime in 2008. It was not until after the DEA suspended its distribution license for three distribution centers in 2007/2008 that Cardinal took steps to implement an electronic suspicious order monitoring program that would stop shipments of suspicious orders.[22]

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[21] 2019 WL 3917575 at *9. Plaintiffs have filed a motion seeking to have this Court adopt Judge Polster's ruling on duties under the CSA as law of the case, See Docs. 189 (motion), 190 (memorandum), and a motion for partial summary judgment establishing those duties in this case, Doc. 1011. Plaintiffs incorporate that briefing, including the standard for granting partial summary judgment, and will not restate those arguments here.

[22] Prior to this time "there was no electronic system for analyzing orders" and "most of the files on customers and orders were on paper, rather than electronic[.]" *See* April 12, 2013 Investigation Report of the Special Demand Committee of the Board of Directors of Cardinal Health, Inc., Doc. 1910-1, Ex. 220 (CAH_MDL_PRIORPROD_HOUSE_0003331, 0003341) (Exhibit 10 at *8).

Cardinal is likely, as was the case in the MDL, to argue the use of the ILR process was supposedly approved by DEA investigators as a CSA compliant report, and that subsequently, the DEA changed its interpretation of the law.[23] Of course, the evidence above establishes that the DEA repeatedly informed Cardinal that reporting suspicious orders did not alone satisfy compliance with the CSA, and, indeed, Cardinal admitted that, by September 2006, it was aware that the ILR Process was not compliant with the CSA because the process resulted in orders being shipped without conducting any due diligence.[24]

In any event, the premise of Cardinal's argument, that the law changed, is incorrect. As Judge Polster found, the duty not to ship a suspicious order without performing due diligence was imposed by the CSA and had not changed over time.[25] And in this case, the record of shipments of suspicious orders by Cardinal to Cabell/Huntington pharmacies noted above could hardly be characterized as substantial compliance with the CSA.[26]

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[23] See SOMs Order at *14 (Exhibit 1).

[24] *See, supra,* pp. 7-8. Cardinal's expert in this case, Brian Reise, a former DEA investigator, agreed that orders identified as suspicious should not be shipped without due diligence being performed. Reise Dep. of Sept. 17, 2020 at 256-57 (Ex. 11).

[25] Evidentiary Order at 25 (Exhibit 2).

[26] Here the ILRs evidence 239 invoiced orders totaling 248,044 dosage units over Cardinal's ingredient limit and therefore suspicious. CAH ILR Summary (Ex. 4A). While, on the factual record presented in the MDL, Judge Polster denied Plaintiffs' motion for summary judgment, SOMs Order at *14, as he subsequently made clear, the ruling was based on "whether Defendants had violated or not substantially complied with their duties under the CSA – not whether the duties themselves had always existed or changed over time." Evidentiary Order at *13. Moreover, as Judge Polster recognized, the thrust of the MDL motion was that Cardinal did not have "any

Under these circumstances, Cardinal clearly violated the CSA. With respect to this case, the shipments to Cabell County and Huntington noted in the CAH ILR Summary did not comply with the provisions of the CSA, and this Court should grant partial summary judgment on this portion of Plaintiffs' claim.

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' request for summary adjudication and should find, as a matter of law, that Cardinal's shipping of suspicious orders as identified in its ILRs violated its duties under the CSA to maintain effective controls against diversion.

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system in place to timely report suspicious orders or prevent shipment of suspicious orders." SOMs Order (Ex. 1 at *13)(emphasis added). Here the focus is on the suspicious orders actually shipped without conducting due diligence and the evidentiary record establishing the violations not whether the system was in compliance.

Dated September 22, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on September 22, 2020, a copy of the foregoing **PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT HOLDING THAT CARDINAL HEALTH DID NOT COMPLY WITH ITS DUTIES UNDER THE CONTROLLED SUBSTANCES ACT** has been filed electronically using the Court's CM/ECF system and will be served *via* the Court's CM/ECF filing system, which will send notification of such filing to the attorneys of record at their e-mail addresses on file with the Court. This filing will also be served on all parties by email to Track2OpioidDefendants@ReedSmith.com and CT2_Opioid_Team@mail-list.com.

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